

New Claims 49 - 51 have been added, and these claims find support in specification at page 11, lines 1 to 14. Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached is captioned "**VERSION WITH MARKINGS TO SHOW CHANGES MADE.**" As can be seen, no new matter has been added. As such, entry of Claims 49-51 is respectfully requested.

Rejections of claims 32-36 and 38-48 under 35 U.S.C. § 102

The Office Action states that Claims 38 and 41-48 remain rejected under 35 U.S.C. § 102(e) as being anticipated by Wang. Specifically, the Office Action asserts that an instructional element does not carry any patentable weight, and, as such, the claims are anticipated by the disclosure of Wang.

In making the rejection, the Office Action asserts that instructional elements do not carry patentable weight.

The law is explicitly clear that printed material constitutes a limitation upon which patentability may be predicated. As stated in *In re Lowry*, the courts are "notably weary of reiterating this point". How the US Patent and Trademark Office should examine claims containing printed matter elements is also summarized very explicitly in *In re Lowry*¹:

The Patent and Trademark Office (PTO) must consider all claim limitations when determining patentability of an invention over the prior art. ² The PTO may not disregard claim limitations comprised of printed matter. ³(underlining added by Applicants).

As such, elements containing printed material do have patentable weight and cannot simply be removed from a claim before a claim is examined. The phrase "printed matter" makes it abundantly clear that it does not matter onto which substrate the printing is on.

The key question for patentability of claims reciting printed matter is whether or not a "*functional relationship*" exists between the printed matter and the other elements of a

¹ 32 U.S.P.Q.2D (BNA) 1031

² Gulack, 703 F.2d at 1385.

³ See Gulack, 703 F.2d at 1384; see also *Diamond v. Diehr*, 450 U.S. 175, 191 (1981).

claim^{4,5}.

The claims of the instant invention are directed to, *inter alia*, a kit containing a) biochemical reagents, and b) instructions for the use of the reagents in a specific method that has already been found patentable in the parent application. As will be demonstrated below, the instructions to use the reagents in a patentable method impart functionality to the biochemical reagents of the kit.

The Applicant respectfully asserts that one of skill in the art would not know how to use the reagents of the claimed kit without instructional element of the claims. As such, the instructions do not merely provide an intended use of the reagents of the kit: the instructions have a very meaningful functional relationship with the reagents of the kit because they actually show how to use the kit.

In the real world situation, where one of skill in the art is a laboratory technician or post-doctoral researcher, one of skill in the art would have no idea how to mix the components of a kit together or with other reagents in a meaningful way, how to set up a reaction, which temperatures and times to incubate the reaction or how to stop the reaction without instructions. One of skill in the art, upon finding a kit with no instructions would likely spend a significant amount of time trying to find the methods before using the kit. As such, the reagents of a kit cannot be effectively used without instructions and the instructions should be considered an integral and necessary part of the kit. In other words, the reagents and instructions for their use have a very meaningful relationship: the reagents can only be used with the instructions.

As such, the instant claims must be considered as having “instructions” as a limitation.

Having established that a claim element reciting instructions carries patentable weight, the claim *in its entirety* is now evaluated with respect to the cited prior art.

It is well established that “[a] claim is anticipated only if each and every element as

⁴ In re Gulack, 217 U.S.P.Q 401 (1983),

set forth in the claim is found, either expressly or inherently described, in a single prior art reference.”⁶ As such, any art cited must describe a kit containing reagents and an instructional element to use the reagents in the recited method.

In the present case, Wang fails to teach a kit containing an instructional element of the present claims because Wang is concerned with an entirely different method. As such, Wang fails to teach each and every element of the claims.

Because Wang fails to teach each and every element of the claimed kit, e.g., the instructions, Wang fails to anticipate Claims 38 and 41-48 under 35 U.S.C. § 102(e).

Claims 32-36 and 39-40 have been rejected under 35 U.S.C. § 102(e) as being anticipated by Phillips. In making this rejection, the Examiner asserts that the recited instructional element is not deemed to hold any patentable weight. As demonstrated above, in the present situation the instructional element holds patentable weight just like any other element. Phillips fails to teach a kit containing an instructional element of the present claims because Phillips is concerned with an entirely different method. As such, Phillips fails to teach each and every element of the claims. Because Phillips fails to teach each and every element of the claimed kit, e.g., the instructions, Phillips fails to anticipate Claims 32-36 and 39-40 under 35 U.S.C. § 102(e).

The Office Action further states that the disclosures of Wang or Phillips could be used as a set of instruction for use with a kit of the present invention. However, any method suggested by these references is different from the method recited in the claimed kits. As such, the Wang and Phillips references still do not anticipate the claimed invention.

The Applicant submits that the rejection of claims 32-36 and 38-48 under 35 U.S.C. § 102 has been adequately addressed in view of the remarks set forth above. The Examiner is thus respectfully requested to withdraw the rejection.

⁵ 32 U.S.P.Q.2D (BNA)

⁶ *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ 2d 1051, 1053 (Fed. Cir. 1987), *cert. denied*, 481 U.S. 1052 (1987). *See also, Scripps Clinic and Research Foundation v. Genentech, Inc.*, 18 USPQ 2d 1001 (Fed. Cir. 1991).

Conclusion

The Applicant respectfully submits that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone Gordon Stewart at 650 485 2386. The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§ 1.16 and 1.17 which may be required by this paper, or to credit any overpayment, to Deposit Account No. 50-1078.

Respectfully submitted,

Date: _____

7.3.02

By: _____

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

Please add the following new claims:

--49. (New) The kit according to Claim 32, wherein said kit further comprises an agent that inactivates a reverse transcriptase.

50. (New) The kit according to Claim 49, wherein said agent irreversibly inactivates a reverse transcriptase.

52. (New) The kit according to Claim 49, wherein said agent reversibly inactivates a reverse transcriptase. --